



PROMETHEUS™ Serum Infliximab /HACA Measurement

Ordering Information

PROMETHEUS™ Serum Infliximab/HACA Measurement

Catalog # 3130

- Serum infliximab measurement is necessary when assessing the presence or absence of HACA.

PROMETHEUS™ Serum Infliximab Measurement (only)

Catalog # 3120

Specimen:

Minimum 2mL serum; collect in serum separator (SST) or red top tube.

Shipping and Handling:

Serum sample can be sent ambient, refrigerated, or frozen if separated from the red cells. The specimen must be received at Prometheus within 7 days of collection.

To order transportation kits, contact Prometheus Client Services at (888) 423-5227.

Turn Around Time:

Approximately 8 days from receipt by Prometheus.

Test Results:

Test results will be faxed and/or mailed to the ordering physician's address. For immediate test results on-line with notification via e-mail, register for ProNet by calling Prometheus Client Services at (888) 423-5227 or log on to our website.

<http://www.prometheuslabs.com/>

Intended Use:

Serum infliximab concentrations may vary among equally dosed patients.¹ Measuring serum infliximab levels can aid physicians in determining the dose of infliximab and guide infusion intervals.^{1,2} The HACA portion of the test detects Human Anti-Chimeric Antibodies (antibodies against infliximab). Patients that develop HACA may experience infusion reactions and/or a reduced duration of efficacy of infliximab.²

- **Infliximab trough levels correlate with response to therapy:**

A study in rheumatoid arthritis patients demonstrates improved response at week 54 in the majority of patients with infliximab trough levels >10 µg/mL.¹

- **Infliximab concentrations correlate with duration of efficacy:**

Infliximab concentrations of 12 µg/mL or higher 4 weeks post-infusion show a median duration of response of 81.5 days as compared with 68.5 days for patients with lower concentrations.²

- **HACA levels correlate with increased probability of adverse events:**

A study in Crohn's disease predicted a 2.40 fold greater risk of infusion reaction in patients with HACA concentrations of 8 µg/mL or higher.²

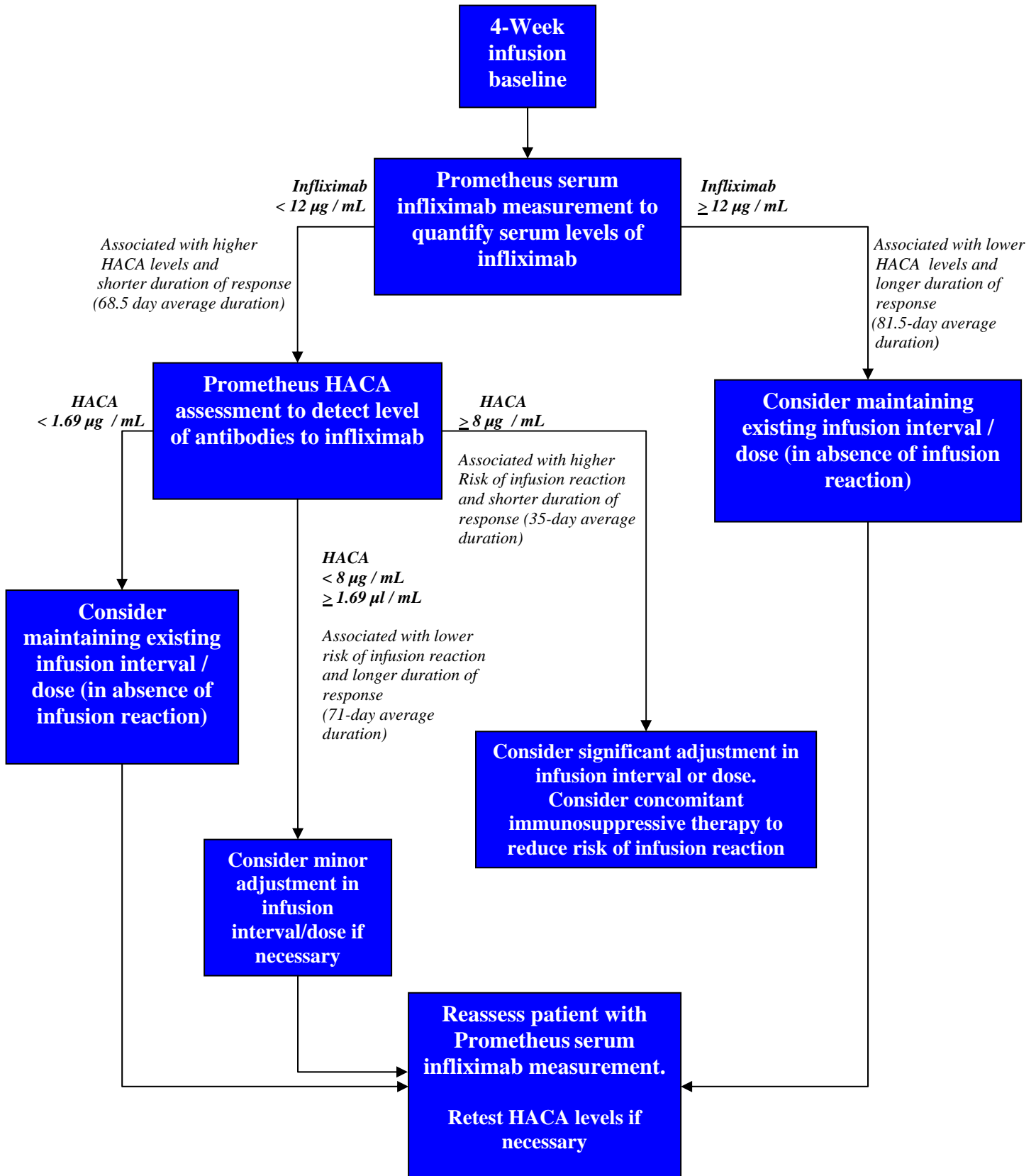
- **HACA levels correlate with a reduced response to therapy:**

HACA concentration of 8 µg/mL or higher showed a median response of 35 days as compared to 71 days for Crohn's patients with lower HACA concentrations.²

References:


- 1) St. Clair EW et al. The relationship of serum infliximab concentrations to clinical improvement in rheumatoid arthritis. *Arthritis and Rheumatism*. 2002;46(6):1451-1459.
- 2) Baert F et al. Influence of immunogenicity on the long-term efficacy of infliximab in Crohn's disease. *The New England Journal of Medicine*. 2003; Vol 348:601-608.

PROMETHEUS™ Serum Infliximab / HACA Measurement in Crohn's Disease



Adapted from: Baert F et al. Influence of immunogenicity on the long-term efficacy of infliximab in Crohn's disease. *The New England Journal of Medicine*. 2003; Vol 348:601-608.

Sample Test Report

 PROMETHEUS™ Therapeutics & Diagnostics	Test Results	SAMPLE REPORT
	PROMETHEUS™ Serum Infliximab / HACA Measurement	
9410 Carroll Park Drive San Diego CA 92121 Toll Free: 888/423-5227 www.prometheuslabs.com		
Patient & Order Information		Report Recipient
Order ID	851731	Example Physician M.D. Prometheus Laboratories Inc. 9410 Carroll Park Drive
Patient	Test, Patient	
DOB	01/01/1950	San Diego, CA 92121 USA
SSN	Sex ?	
Institution ID	XXXXXX	Prometheus ID XXXXXX
Ordered	01/13/2006	Completed 01/16/2006
Ordered By	Example Physician M.D.	
ICD9 Codes	V72.6	
Sample ID: SH01130398	Collection Date: 01/12/2006	(Serum) Institution Sample ID:
Test Ordered: PROMETHEUS™ Serum Infliximab / HACA Measurement		
Results: Undetectable infliximab / Positive HACA		
Assay Results:	Assay	Value
	Serum Infliximab Measurement	< 1.40 mcg/ml
	Human Anti-Chimeric Antibody (HACA)	13.93 mcg/ml equivalents
		Reference Range
		<1.40 mcg/ml
		<1.69 mcg/ml equivalents
<ul style="list-style-type: none">• Serum infliximab levels equal to or greater than 12.0 mcg/ml at 4 weeks post infusion correlate with a longer duration of response (1).• Human Anti-Chimeric Antibodies (HACA) against infliximab detected at concentrations equal to or greater than 8.0 mcg/ml before infusion predict a shorter duration of response and higher risk of infusion reactions (1).• Data suggests treatment with immunosuppressive agents; azathioprine, 6-MP or methotrexate, may prevent infusion reactions and help maintain clinical efficacy of infliximab (1).		
Reference: (1) Baert, F. M.D., et al. Influence of Immunogenicity on the Long-Term Efficacy of Infliximab in Crohn's Disease. N Engl J Med 2003 348;7:601-608.		
Robert M. Nakamura M.D., Medical Director John C. Spinoso, M.D. Ph.D., Associate Director Bernard Chang M.D., Associate Director	PROMETHEUS™ is a registered trademark of Prometheus Laboratories Inc. Copyright ©2006 Prometheus Laboratories Inc. All Rights Reserved. Prometheus Laboratories Inc. is accredited by the College of American Pathologists.	Printed 1/16/2006

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